IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8208

Bartle, C.J. June 29, 2009

Charlotte McKinley ("Ms. McKinley" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul R. Chu, M.D. Based on an echocardiogram dated April 2, 2002, Dr. Chu attested in Part II of Ms. McKinley's Green Form that she suffered from severe aortic regurgitation,[3] moderate mitral regurgitation, an

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presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. As Ms. McKinley's aortic valve claim does not present any of the complicating factors necessary to receive Level II benefits, if eligible, she would be entitled only to Level I benefits. See Settlement Agreement §§ IV.B.2.c.(1)(a) & IV.B.2.c.(2)(a).

abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Dr. Chu also attested that claimant did not have aortic sclerosis, which is a reduction factor that requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i). Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits with respect to her mitral valve claim, or Matrix A-1, Level I benefits with respect to her aortic valve claim.[4]

In the report of claimant's echocardiogram, Dr. Chu stated that Ms. McKinley had "[s]evere aortic insufficiency," which he estimated as 56%. Under the definition set forth in the Settlement Agreement, severe aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is greater than 49% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22 & IV.B.2.c(2)(a). Dr. Chu also stated that Ms.

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's findings of an abnormal left atrial dimension and a reduced ejection fraction, both of which are conditions which would qualify for a Level II claim, the only remaining issue is claimant's level of mitral regurgitation.

Alternatively, under the Settlement Agreement, a claimant is eligible for Level I benefits for damage to the aortic valve if he or she is diagnosed with severe aortic regurgitation and no complicating factors. See id. § IV.B.2.c.(1).

McKinley had "[m]oderate mitral regurgitation," which he estimated as 33%. Under the Settlement Agreement, moderate mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is between 20% and 40% of the Left Atrial Area ("LAA"). See id. §§ I.22 & IV.B.2.c(2)(b). Dr. Chu further stated that "the left atrium is mildly dilated measuring 4.3 cm in the parasternal long axis view and 5.7 cm in the apical long axis view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. § IV.B.2.c.(2)(b). Dr. Chu also estimated claimant's ejection fraction as 50%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. Finally, in contrast to the Green Form, Dr. Chu noted that claimant had a "[s]clerotic aortic valve." Aortic sclerosis is a reduction factor with respect to an aortic valve claim if the claimant is 60 years of age or older at the time he or she is first diagnosed as FDA positive.[5] See id. § IV.B.2.d.(2)(c)i)c). A finding of aortic sclerosis requires the payment of benefits on Matrix B-1. See id.

In May 2003, the Trust forwarded the claim for review

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5. Claimant concedes that she was 73 years old at the time of diagnosis.

by Benjamin S. Citrin, M.D., one of its auditing cardiologists. In audit, Dr. Citrin concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. Specifically, he stated that "[t]he Nyquist limit is set too low at 51 and exaggerates the degree of [mitral regurgitation] which fits criteria for mild." Dr. Citrin, however, found that there was a reasonable medical basis for finding an abnormal left atrial dimension and a reduced ejection fraction. With respect to claimant's level of aortic regurgitation, Dr. Citrin concluded that there was no reasonable medical basis for the attesting physician's finding of severe aortic regurgitation because "[t]he JH/LVOTH is less than 50%."[6] In the Report of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue, Dr. Citrin also found that claimant had aortic sclerosis.

Based on Dr. Citrin's diagnoses of mild mitral regurgitation and moderate aortic regurgitation, the Trust issued a post-audit determination denying Ms. McKinley's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7]

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6. In Dr. Citrin's Certification, the words "less than or = 49%" are handwritten, purportedly by Dr. Citrin.

7. Claims placed into audit on or before December 1, 2002 are (continued...)

In contest, claimant submitted a verified expert opinion by Robert B. Norris, M.D.[8] Therein, Dr. Norris stated that, at "loop 215 of 247," claimant had moderate mitral regurgitation, which he measured as 21%.[9] Claimant also argued that Dr. Chu's finding of moderate mitral regurgitation was reasonable because it was consistent with a November 23, 2001 echocardiogram that claimant received under the Trust's Screening Program, which stated that she had moderate mitral regurgitation.[10] See Settlement Agreement § IV.A.

Although not required to do so, the Trust submitted the claim to the auditing cardiologist for a second review. Dr. Citrin submitted a declaration, in which he again concluded that "[c]laimant's mitral regurgitation is well below the threshold

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governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. McKinley's claim.

8. In contest, claimant did not dispute the Trust's denial of her aortic valve claim or rebut Dr. Citrin's specific findings regarding her aortic valve. In show cause, claimant disputed Dr. Citrin's finding of moderate aortic regurgitation, but she never challenged Dr. Citrin's finding of aortic sclerosis.

9. Dr. Norris also stated that, at "loop 36 of 247," claimant had "moderate aortic regurgitation," which he measured as 50%. Under the Settlement Agreement, however, this level of aortic regurgitation constitutes severe aortic regurgitation.

10. Claimant submitted a copy of the echocardiogram report.

for moderate mitral regurgitation and that the regurgitant jet area/left atrial area ratio is no more than 15%." Dr. Citrin further stated that:

> I again analyzed the frame planimetered by Claimant's sonographer and relied upon by Claimant's Attesting Cardiologist and expert. As the ECG [echocardiogram] reading makes apparent, the planimetered frame depicts Claimant's left atrium in a post ventricular contraction (PVC) or during a skipped or shortened beat of the heart. Because the dynamics of the heart are altered and the flow of blood becomes chaotic during a PVC, it is inappropriate to measure the level of mitral regurgitation at this juncture. Accordingly, the frame planimetered . . . is not representative and may not be relied upon for an accurate assessment of the level of mitral regurgitation.[11]

The Trust then issued a final post-audit determination, again denying Ms. McKinley's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. McKinley's claim should be paid. On April 14, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3431 (Apr. 14, 2004).

Once the matter was referred to the Special Master, the

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11. Dr. Citrin was not asked to re-review claimant's level of aortic regurgitation.

Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[12] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. at Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings of severe aortic regurgitation and/or moderate mitral regurgitation. See id. at Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the

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12. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Trust's final determination and may grant other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. McKinley argues that her expert, Dr. Norris, made actual measurements, which, in her view, are required under the Settlement Agreement. Claimant further contends that Dr. Citrin merely substituted his opinion for that of the attesting physician without providing any explanation for his findings. Finally, claimant contends that the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational or senseless from any medical perspective."

The Trust counters that the frame relied on by Dr. Norris was not representative of claimant's echocardiogram study. The Trust also contends that Dr. Citrin complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram.[13]

The Technical Advisor, Dr. Vigilante, reviewed

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13. In its show cause submissions, the Trust also argues that under Federal Rule of Civil Procedure 26(a)(2), physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007).

claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

> I digitized representative cardiac cycles and planimetered the RJA and LAA. Loop 215 referenced by Dr. Norris was a still frame and non-representative jet of mitral regurgitation. This appeared to occur in relation to a ventricular ectopic beat. Instead, I measured representative RJA's and LAA's in appropriate and non-ectopic cardiac cycles in the apical four chamber and apical two chamber views. The mitral regurgitation jet was most impressive in the apical four chamber view. The RJA/LAA ratio was 18% in the cardiac cycle in which the mitral regurgitation jet appeared most impressive. A large majority of representative cardiac cycles demonstrated that the RJA/LAA ratio was less than 15%.

Dr. Vigilante, however, concluded that there was a reasonable medical basis for the attesting physician's finding of severe aortic regurgitation. Dr. Vigilante stated that:

> Several representative frames of the aortic regurgitation jet in the parasternal long axis view were reviewed in detail. I measured the JH as well as LVOTH in several representative cycles and found the JH/LVOTH ratio was 50%.

Dr. Vigilante also noted the presence of "obvious aortic sclerosis with significant thickening and calcification of the aortic valve particularly the non-coronary aortic valve leaflet."

In response to the Technical Advisor's Report, the Trust argues that Dr. Vigilante's finding of mild mitral

regurgitation supports the denial of claimant's Level II mitral valve claim. The Trust also concedes that Dr. Vigilante's finding of severe aortic regurgitation supports a Level I claim. The Trust, however, maintains that Ms. McKinley's aortic valve claim must be paid on Matrix B-1 because of the presence of aortic sclerosis, as found by the Technical Advisor and the auditing cardiologist and memorialized in the echocardiogram report of the attesting physician.

After reviewing the entire Show Cause Record before us, we find that claimant has failed to establish a reasonable medical basis for her mitral valve claim. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Vigilante.[14] Specifically, claimant does not challenge Dr. Vigilante's findings that "[t]he RJA/LAA ratio was 18% in the cardiac cycle in which the mitral regurgitation jet appeared most impressive" and that "[a] large majority of representative cardiac cycles demonstrated that the RJA/LAA ratio was less than 15%." Nor does claimant adequately contest Dr. Citrin's findings that claimant's physicians relied on a "planimetered frame [that] is not representative and may not be relied upon for an accurate assessment of the level of mitral regurgitation" and that "[t]he Nyquist limit is set too low at 51 and exaggerates the degree of [mitral regurgitation] which fits criteria for mild." On this

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14. Despite an opportunity to do so, claimant did not submit any response to the Technical Advisor Report. See Audit Rule 34.

basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her mitral valve claim.[15]

We also disagree with claimant's definition of reasonable medical basis. Without any discussion, claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court simply addressed the circumstances under which the court would appoint an impartial expert witness to be presented to the jury and, therefore, the case is not apposite. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. One of the definitions, however, is "not guided by reason." The word "unreasonable" does not always mean "irrational" as claimant would have us believe and it does not mean that here. We are not persuaded that either Gallagher or Black's supports claimant's position.

We further disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA," which is based on the grading

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15. For this reason as well, we find that Dr. Citrin provided a sufficient explanation to support his finding of mild mitral regurgitation and, thus, did not simply substitute his opinion for that of the attesting physician.

system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 (Nov. 14, 2002).

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits for her mitral valve claim because the attesting physician's findings are supported by the echocardiogram conducted in the Screening Program for Fund A benefits under the Settlement Agreement. Section IV.A.1.c. of the Settlement Agreement provides that the sole benefit which a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Thus, by the plain terms of the Settlement Agreement, a Screening

Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

This conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See Settlement Agreement § IV.B.1. Further, adopting claimant's position would be inconsistent with PTO No. 2662 (Nov. 26, 2002), in which we mandated a 100% audit requirement for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

We, however, conclude that claimant has established a reasonable medical basis for her aortic valve claim. Claimant's attesting physician, Dr. Chu, reviewed claimant's echocardiogram and found that claimant had severe aortic regurgitation measured at 56%. Claimant's expert, Dr. Norris, also measured claimant's level of aortic regurgitation as 50%. Although the Trust contested the conclusions of the attesting physician and expert, Dr. Vigilante confirmed the diagnosis of severe aortic regurgitation, which he measured as 50% in the parasternal long axis view. As stated above, aortic regurgitation is considered

severe if it is measured as greater than 49% in the parasternal long axis view. See Settlement Agreement §§ I.22 & IV.B.2.c(2)(a). Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her attesting physician's finding of severe aortic regurgitation.

We further conclude that claimant has not met her burden in proving that she did not have aortic sclerosis. The presence of aortic sclerosis was found by Drs. Citrin and Vigilante, and also memorialized in the echocardiogram report of the attesting physician. Claimant failed to challenge Dr. Vigilante's specific conclusion that "[t]here was obvious aortic sclerosis with significant thickening and calcification of the aortic valve particularly the non-coronary aortic valve leaflet." Accordingly, claimant's Level I claim must be paid on Matrix B-1.

For the foregoing reasons, claimant has not met her burden in proving that there is a reasonable medical basis for finding moderate mitral regurgitation. However, she has met her burden to establish that there is a reasonable medical basis for finding severe aortic regurgitation. Finally, she has not met her burden to demonstrate that there is a reasonable medical basis for finding that she does not have aortic sclerosis. Therefore, we will affirm the Trust's denial of the claim of Charlotte McKinley for Matrix A-1, Level II benefits and reverse the Trust's denial of her claim for Level I benefits, which must be paid on Matrix B-1.